

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent of:	McGee <i>et al.</i>	Confirmation No.:	1490
U.S. Patent No.:	7,601,841 B2	Art Unit:	1625
Issued:	October 13, 2009	Examiner:	Seaman, D. Margaret
Application No.:	10/719,997		
For: QUINOLINYL AND BENZOTHAZOLYL MODULATORS		Attorney Docket No.:	11134-096-999 (CAM: 893053-999097)

**REQUEST FOR RECONSIDERATION OF
PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)**

MAIL STOP PATENT EXT.

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a second request for reconsideration of patent term adjustment for the above-identified United States Patent No. 7,601,841 B2 (“the ’841 patent”), which was granted on Application No. 10/719,997 (“the ’997 application”). The United States Patent and Trademark Office (“PTO”) mailed a communication on August 11, 2009 (“August 11th Communication,” Exhibit A) in which the PTO responded to Applicants’ “REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b),” mailed February 17, 2009, by stating that a decision on Applicants’ request was being held in abeyance until after the actual patent date. In the August 11th Communication, the PTO stated that a written request for reconsideration of the patent term adjustment for PTO failure to issue the patent within three years could be filed within two months of the issue date of the patent. The ’841 patent issued October 13, 2009, and, therefore, this second request, filed December 11, 2009, is timely filed within two months of October 13, 2009.

The patent term adjustment under 35 U.S.C. § 154(b) indicated on the face of the ’841 patent is 326 days. Applicants hereby respectfully requests reconsideration of the patent

term adjustment under 35 U.S.C. § 154(b). Specifically, Applicants believe that the patent term adjustment should be increased by 83 days to a total of **409** days.

The basis for this petition and the required fees are set forth herein.

REMARKS

A request for reconsideration of patent term adjustment under 37 C.F.R. § 1.705(d) must be accompanied by:

- (1) the fee set forth in 37 C.F.R. § 1.18(e); and
- (2) a statement of the facts involved, specifying:
 - (i) the correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment;
 - (ii) the relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) to which the patent is entitled;
 - (iii) whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and
 - (iv)(A) any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704; or
 - (B) that there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704.

See 37 C.F.R. § 1.705(b).

In support of this request, Applicants submit the following:

1. Fee Required Under 37 C.F.R. § 1.705(b)(1)

No fee is believed to be due with this request, since the fee as set forth in 37 C.F.R. § 1.18(e) was submitted with Applicants' first request for reconsideration of patent term adjustment as acknowledged in the PTO's August 11th Communication (*see* Exhibit A). However, should the Commissioner determine otherwise, the Commissioner is hereby

authorized to charge any required fee(s) to Jones Day Deposit Account No. 50-3013
(referencing order number 893053-999097).

2. Statement Required Under 37 C.F.R. § 1.705(b)(2)

Pursuant to 37 C.F.R. § 1.705(b)(2), Applicants submit the following statement of facts in support of this application:

(i) The correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment are as follows:

1. Correct patent term adjustment:

The correct patent term adjustment is 409 days, which is attributable to (a) the failure of the PTO to mail a notification under 35 U.S.C. § 132 not later than fourteen months after the date on which the '997 application was filed under 35 U.S.C. 111(a) (delay under 37 C.F.R. § 1.702(a)(1)), and the failure of the PTO to issue the '841 patent not later than four months after the date on which the issue fee was paid and all outstanding requirements were satisfied (delay under 37 C.F.R. § 1.702(a)(4)) (collectively, the "A delay"); and (b) the failure of the PTO to issue a patent within three years of the actual filing date of the '997 application (delay under 37 C.F.R. § 1.702(b)) (the "B delay").

2. Bases under 37 C.F.R. § 1.702 for the adjustment:

(a) Delay under 37 C.F.R. § 1.702(a) (the "A delay")

The A delay by the PTO under 37 C.F.R. § 1.702(a) is 201 days.

As acknowledged by the PTO in its calculation of the patent term adjustment, the PTO failed to mail a notification under 35 U.S.C. § 132 within fourteen months from the date of filing of the '997 application. *See* PTO's Patent Application Information Retrieval page for U.S. Application No. 10/719,997, at Patent Term Adjustment History ("PTO PAIR Adjustment," Exhibit B). The '997 application was filed under 35 U.S.C. § 111(a) on November 20, 2003. The first notification under 35 U.S.C. § 132 (a Restriction Requirement) was mailed by the PTO on April 13, 2005. Accordingly, the PTO did not mail a notification under 35 U.S.C. § 132 or a notice of

allowance under 35 U.S.C. § 151 within fourteen months after the date on which the application was filed (or by January 20, 2005), and thus, the term of the patent should have been adjusted because the notification under 35 U.S.C. § 132 was delayed by 83 days, which is the period of time from January 20, 2005 to April 13, 2005. 37 C.F.R. § 1.702(a)(1).

As acknowledged by the PTO in its calculation of the patent term adjustment, the PTO failed to issue a patent not later than four months after the date on which the issue fee was paid under 35 U.S.C. § 151 and all outstanding requirements were satisfied for the '997 application (*see* PTO PAIR Adjustment, Exhibit B). The issue fee payment for the '997 application was received on February 17, 2009, which is also the date on which all outstanding requirements were satisfied for the '997 application. The '997 application issued as the '841 patent on October 13, 2009. Accordingly, the PTO did not issue a patent not later than four months after the date on which the issue fee was paid (or by June 17, 2009), and thus, the term of the patent should have been adjusted because issuance of the '841 patent was delayed by 118 days, which is the period of time from June 17, 2009 to October 13, 2009. 37 C.F.R. § 1.702(a)(4).

In sum, the A delay, that is, the delay under 37 C.F.R. §§ 1.702 (a)(1) and 1.702(a)(4), is 83 plus 118 or 201 days.

(b) Delay under 37 C.F.R. § 1.702(b) (the “B delay”)

The B delay by the PTO under 37 C.F.R. § 1.702(b) is 569 days.

The '997 application was filed under 35 U.S.C. § 111(a) on November 20, 2003. A Request for Continued Examination (“RCE”) under 35 U.S.C. § 132(b) was filed on June 11, 2008. The filing of a RCE cuts-off the applicant’s ability to accumulate any additional patent term adjustment against the three-year pendency provision, but does not otherwise affect patent term adjustment.” *See* MPEP § 706.07(h) XIII A. “Comparison With The Transitional Procedure Set Forth In 37 CFR 1.129(a) And The CPA Procedure Set Forth In 37 CFR 1.53(d).” Accordingly, the PTO failed to issue a patent within three years of the date on which the application was filed (or by November 20, 2006), and thus, the term of the patent should have been adjusted because issuance was delayed by 569 days, which is the period of time from November 20, 2006 to June 11, 2008. 37 C.F.R. § 1.702(b). The full 569 day

delay in issuance of the patent was not included by the PTO in its calculation of patent term adjustment. Instead, the PTO included in its calculation a delay of only 486 days, presumably because the PTO considered the delay under 37 C.F.R.

§ 1.702(a)(1) (83 days) to overlap the delay under 37 C.F.R. § 1.702(b) (569 days), and therefore subtracted 83 days from the delay under 37 C.F.R. § 1.702(b) (569 – 83 = 486 days; *see* PTO PAIR Adjustment, Exhibit B). Applicants respectfully submit that these delays do not overlap, as explained below.

(c) There are no overlapping days in the delay periods

According to 35 U.S.C. § 154(b)(2)(A): “To the extent that periods of delay attributable to grounds specified in paragraph (1) *overlap*, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.” *See* 35 U.S.C. § 154(b)(2)(A).

According to 37 C.F.R. § 1.703(f): “The term of a patent entitled to adjustment under § 1.702 and this section shall be adjusted for the sum of the periods calculated under paragraphs (a) through (e) of this section, to the extent that such periods are not *overlapping*” (emphasis added). *See* 37 C.F.R. § 1.703(f).

Applicants respectfully submit that under controlling case law the A delay under 37 C.F.R. §§ 1.702(a)(1) and 1.702(a)(4) does not overlap the B delay under 37 C.F.R. § 1.702(b) for the '997 application.

In *Wyeth et al. v. Dudas* (hereinafter *Wyeth*) the District Court for the District of Columbia clarified the meaning of 35 U.S.C. § 154(b)(2)(A). *See Wyeth et al. v. Dudas*, Civil Action No. 07-1492 (JR), United States District Court for the District of Columbia, 2008 U.S. Dist. LEXIS 76063 (D.D.C., September 30, 2008), attached hereto as Exhibit C. In *Wyeth*, the court held that: “The only way that periods of time can ‘overlap’ is if they occur on the same day. If an ‘A delay’ occurs on one calendar day and a ‘B delay’ occurs on another, they do not overlap.” *Wyeth*, 2008 U.S. Dist. LEXIS 76063, 9-10.

Turning to the '997 application, the period of delay under 37 C.F.R. § 1.702(a)(1) occurred from January 20, 2005, fourteen months from the date on which the application was filed, to April 13, 2005, the date on which a Restriction

Requirement was mailed by the PTO. The period of delay under 37 C.F.R.

§ 1.702(a)(4) occurred from June 17, 2009, four months after the date on which the issue fee was paid, to October 13, 2009, the date of issuance of the patent. 37 C.F.R. § 1.702(a)(4). The period of delay under 37 C.F.R. § 1.702(b) occurred from November 20, 2006, three years from the date on which the application was filed, to June 11, 2008, the date a Request for Continued Examination was filed. Thus, the A delay under 37 C.F.R. §§ 1.702 (a)(1) and 1.702 (a)(4) (January 20, 2005 to April 13, 2005, and June 17, 2009 to October 13, 2009, respectively) occurred on different calendar days than the B delay under 37 C.F.R. § 1.702(b) (November 20, 2006 to June 11, 2008). Consequently, under 35 U.S.C. § 154(b)(2)(A), the delay under 37 C.F.R. § 1.702(a) does not overlap the delay under 37 C.F.R. § 1.702(b) for the '997 application, and therefore the total delay under 37 C.F.R. § 1.702 for the adjustment should be a summation of the delays under 37 C.F.R. §§ 1.702(a)(1) and 1.702(a)(4) and 37 C.F.R. § 1.702(b), or 770 days (the sum of 83, 118 and 569 days).

(ii) The relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) are as follows:

1. Adjustment under 37 C.F.R. §§ 1.703(a) through (e):

An adjustment is sought under 37 C.F.R. § 1.703(a)(1), which provides, in relevant part, that the period of adjustment is “[t]he number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first.”

The patent term adjustment calculated by the PTO correctly included the time period under 37 C.F.R. § 1.702(a)(1) for the period beginning January 20, 2005 (fourteen months after the date on which the '997 application was filed) and ending April 13, 2005, the date the Restriction Requirement was mailed from the PTO. Applicants confirm that this period consists of 83 days.

An adjustment is sought under 37 C.F.R. § 1.703(a)(6), which provides, in relevant part, that the period of adjustment is “[t]he number of days, if any, in the period beginning on the day after the date that is four months after the date the issue

fee was paid and all outstanding requirements were satisfied and ending on the date a patent was issued.”

The patent term adjustment calculated by the PTO correctly included the time period under 37 C.F.R. § 1.702(a)(4) for the period beginning June 18, 2009 (the day after the date that is four months after the date the issue fee was paid for the ’997 application) and ending October 13, 2009, the date the ’997 application issued as the ’841 patent. Applicants confirm that this period consists of 118 days.

An adjustment is sought under 37 C.F.R. § 1.703(b), which provides, in relevant part, that “the period of adjustment under 37 C.F.R. § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a)...and ending on the date a patent was issued.”

Applicants submit that this period consists of 569 days. Applicants further submit that the A delay under 37 C.F.R. § 1.702(a) does not overlap the B delay under 37 C.F.R. § 1.702(b), as explained above.

Accordingly, Applicants believe that the delays attributable to the PTO under 37 C.F.R. § 1.702(a) and 37 C.F.R. § 1.702(b) total 770 days (the sum of 83, 118 and 569 days), not 687 days as calculated by the PTO.

2. Adjustment under 37 C.F.R. § 1.703(f):

As discussed in section (i) above, Applicants believe that the total delay by the PTO under 37 C.F.R. § 1.702(a) and 37 C.F.R. § 1.702(b) (delay A plus delay B) is 770 days. As discussed in section (iv) below, Applicants believe that the total delay attributable to Applicants under 37 C.F.R. § 1.704 is 361 days. Applicants believe that the total period of adjustment due under 37 C.F.R. § 1.703(f) is 409 days, which is the sum of the periods by the PTO calculated under 37 C.F.R. §§ 1.702(a) through (e) (*i.e.*, 770 days), to the extent that such periods are not overlapping, less the sum of the periods calculated under Section 1.704 (*i.e.*, 361 days).

(iii) The ’997 application is not subject to a terminal disclaimer.

(iv) The circumstances during the prosecution of the '997 application that might constitute a failure to engage in reasonable efforts to conclude processing or examination of the '997 application as set forth in 37 C.F.R. § 1.704 are believed to consist of the following:

1. a delay of 34 days by Applicants under 37 C.F.R. § 1.704(b) due to Applicants' payment of a late filing fee on May 13, 2004 in response to the Notice to File Missing Parts of Nonprovisional Application mailed on January 9, 2004;
2. a delay of 85 days by Applicants under 37 C.F.R. § 1.704(b) due to Applicants' filing of an Amendment and Response on December 9, 2005 in response to the non-final Office Action mailed on June 15, 2005;
3. a delay of 92 days by Applicants under 37 C.F.R. § 1.704(b) due to Applicants' filing of an Amendment and Response on August 28, 2006 in response to the non-final Office Action mailed on February 28, 2006;
4. a delay of 58 days by Applicants under 37 C.F.R. § 1.704(b) due to Applicants' filing of an Amendment and Response on April 19, 2007 in response to the non-final Office Action mailed on November 20, 2006; and
5. a delay of 92 days by Applicants under 37 C.F.R. § 1.704(b) due to Applicants' filing of an Amendment and Response on January 23, 2008 in response to the non-final Office Action mailed on July 23, 2007.

37 C.F.R. § 1.704(b) provides, in relevant part: "[A]n applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of three months that are taken to reply to any notice or action by the Office making any rejection, objection, argument, or other request, measuring such three-month period from the date the notice or action was mailed or given to the applicant, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date that is three months after the date of mailing or transmission of the Office communication notifying the applicant of the rejection, objection, argument, or other request and ending on the date the reply was filed."

The patent term adjustment calculated by the PTO correctly included the above time periods under 37 C.F.R. § 1.704(b) (*see* PTO PAIR Adjustment, Exhibit B). Applicants confirm that the sum of the above time period consists of 361 days.

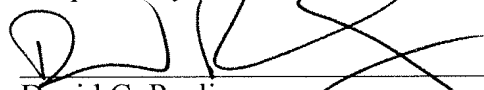
CONCLUSION

In summary, the total delay under 37 C.F.R. § 1.702(a) and 37 C.F.R. § 1.702(b) is 770 days, the total delay attributable to Applicants under 37 C.F.R. § 1.704 are 361 days, and thus the total period of adjustment due under 37 C.F.R. § 1.703(f) is believed to be 409 days. Accordingly, Applicants respectfully request an adjustment of patent term under 37 C.F.R. § 1.703(f) totaling 409 days.

Applicants submit that the issues raised in this second request for reconsideration of patent term adjustment are timely raised under 37 C.F.R. § 1.705(d). No fee is believed to be due with this request, as acknowledged in the PTO's August 11th Communication (*see* Exhibit A). However, should the Commissioner determine otherwise, the Commissioner is hereby authorized to charge any required fee(s) to Jones Day Deposit Account No. 50-3013 (referencing order number 893053-999097).

Date: December 11, 2009

Respectfully submitted,



David C. Pauling

For: Anthony M. Insogna (Reg. No. 35,203)

JONES DAY

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EXHIBIT A:

**August 11th Communication from the PTO (Response to the Request for
Reconsideration of Patent Term Adjustment Under 37 C.F.R. § 1.705(b))**



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AUG 11 2009

OFFICE OF PETITIONS

JONES DAY
222 EAST 41ST ST
NEW YORK NY 10017

In re Application of :
McGee et al. : ON APPLICATION FOR
Application No. 10/719,997 : PATENT TERM ADJUSTMENT
Filed: November 20, 2003 :
Attorney Docket No. 11134-096- :
999 :

This is in response to the APPLICATION FOR PATENT TERM ADJUSTMENT RECONSIDERATION UNDER 37 C.F.R. § 1.705(B) filed February 17, 2009. Applicants submit that the correct patent term adjustment to be indicated on the patent is two hundred ninety (290) days, not zero (0) days as calculated by the Office as of the mailing of the initial determination of patent term adjustment. Applicants request this correction solely on the basis that the Office will take in excess of three years to issue this patent.

As the instant application for patent term adjustment requests reconsideration of the patent term adjustment as it relates to the Office's failure to issue the patent within 3 years of the filing date, the application for patent term adjustment under 37 CFR 1.705(b) is **DISMISSED as PREMATURE.**

Knowledge of the actual date the patent issues is required to calculate the amount, if any, of additional patent term patentee is entitled to for Office failure to issue the patent within 3 years. See § 1.702(b). (This is true even where a request for continued examination (RCE) was filed). The computer will not undertake the § 1.702(b) calculation until the actual date of issuance of the patent has been determined. Likewise, the computer will not calculate any further Office delay under § 1.702(a)(4) or applicant delay under § 1.704(c)(10) until the actual date of issuance of the patent has been determined. As such, the Office cannot make a determination on the correctness of the patent term adjustment until the patent has issued.

Requesting reconsideration of the patent term adjustment to be indicated on the patent under 37 CFR 1.705(b) based on the initial determination of patent term adjustment and a projected issuance date of the patent (or even the filing date of the request for continued examination) is premature. Accordingly, it is appropriate to dismiss as premature such a request.

Rather than file an application for patent term adjustment under 37 CFR 1.705(b) contesting the 37 CFR 1.702(b) calculation at the time of the mailing of the notice of allowance, applicant is advised that they may wait until the time of the issuance of the patent and file a request for reconsideration of the patent term adjustment pursuant to 37 CFR 1.705(d). As the USPTO does not calculate the amount of time earned pursuant to 37 CFR 1.702(b) until the time of the issuance of the patent, the Office will consider any request for reconsideration of the patent term adjustment due to an error in the calculation of 37 CFR 1.702(b) to be timely if the request for reconsideration is filed within two months of the issuance of the patent. However, as to all other bases for contesting the initial determination of patent term adjustment received with the notice of allowance, applicant must timely file an application for patent term adjustment prior to the payment of the issue fee¹.

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e) for consideration of the application for patent term adjustment under 37 CFR 1.705(b).

Any request for reconsideration of the patent term adjustment indicated on the patent must be timely filed within 2 months after issuance pursuant to 37 CFR 1.705(d) and must include payment of the required fee under 37 CFR 1.18(e).

¹ For example, if applicant disputes both the calculation of patent term adjustment under 37 CFR 1.702(a)(1) for Office failure to mail a first Office action or notice of allowance not later than fourteen months after the date on which the application was filed and under 37 CFR 1.702(b) for Office failure to issue a patent within three years of the actual filing date of the application, then applicant must still timely file an application for patent term adjustment prior to the payment of the issue fee to contest the calculation of Office delay in issuing a first Office action or notice of allowance. See 37 CFR 1.705(b) and 35 U.S.C. 154(b)(3)(B). A dispute as to the calculation of the 37 CFR 1.702(a)(1) period raised on request for reconsideration of patent term adjustment under 37 CFR 1.705(d) will be dismissed as untimely filed.

Application No. 10/719,997

Page 3

The Office of Data Management has been advised of this decision. This application is being referred to the Office of Data Management for issuance of the patent.

Telephone inquiries specific to this matter should be directed to Petitions Attorney Charlema Grant at (571) 272-3215.

Kery A Fries

Kery Fries
Senior Legal Advisor Attorney
Office of Patent Legal Administration

EXHIBIT B: PTO PAIR Adjustment

10/719,997	QUINOLINYL AND BENZOTHAZOLYL MODULATORS	11-30-2009::13:47:10
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Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 10/719,997

Filing or 371(c) Date:	11-20-2003	USPTO Delay (PTO) Delay (days):	687
Issue Date of Patent:	10-13-2009	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	361
Post-Issue Petitions (days):	+0	Total PTA (days):	326
USPTO Adjustment(days):	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
09-23-2009	PTA 36 Months	486	
10-13-2009	Patent Issue Date Used in PTA Calculation	118	
08-14-2009	Dispatch to FDC	⬆	
08-11-2009	Mail-Petition Decision - Dismissed	⬆	
08-11-2009	Petition Decision - Dismissed	⬆	
02-17-2009	Petition Entered	⬆	
02-24-2009	Application Is Considered Ready for Issue	⬆	
02-17-2009	Issue Fee Payment Verified	⬆	
02-17-2009	Issue Fee Payment Received		
11-17-2008	Mail Notice of Allowance		
11-14-2008	Notice of Allowance Data Verification Completed		
11-14-2008	Document Verification		
10-28-2008	Information Disclosure Statement considered		
10-28-2008	Reference capture on IDS		
11-06-2008	Date Forwarded to Examiner		
10-28-2008	Response after Non-Final Action		
10-28-2008	Information Disclosure Statement (IDS) Filed		
10-28-2008	Information Disclosure Statement (IDS) Filed		
07-28-2008	Mail Non-Final Rejection		
07-24-2008	Non-Final Rejection		
06-11-2008	Information Disclosure Statement considered		
06-11-2008	Reference capture on IDS		
06-11-2008	Information Disclosure Statement (IDS) Filed		
06-21-2008	Date Forwarded to Examiner		
06-11-2008	Request for Continued Examination (RCE)		
06-21-2008	DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA)		
06-11-2008	Information Disclosure Statement (IDS) Filed		
06-11-2008	Workflow - Request for RCE - Begin		
01-23-2008	Miscellaneous Incoming Letter		
03-11-2008	Mail Notice of Allowance		

02-28-2008	Document Verification	
02-27-2008	Notice of Allowance Data Verification Completed	
01-08-2008	Information Disclosure Statement considered	
01-23-2008	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received	
01-29-2008	Date Forwarded to Examiner	
01-23-2008	Response after Non-Final Action	92
01-23-2008	Request for Extension of Time - Granted	⬆
01-08-2008	Information Disclosure Statement (IDS) Filed	⬆
07-23-2007	Mail Non-Final Rejection	⬆
07-19-2007	Non-Final Rejection	
05-14-2007	Case Docketed to Examiner in GAU	
04-19-2007	Information Disclosure Statement considered	
04-19-2007	Information Disclosure Statement (IDS) Filed	
04-19-2007	Information Disclosure Statement (IDS) Filed	
05-08-2007	Date Forwarded to Examiner	
04-19-2007	Response after Non-Final Action	58
04-19-2007	Request for Extension of Time - Granted	⬆
11-20-2006	Mail Non-Final Rejection	⬆
11-13-2006	Non-Final Rejection	
08-28-2006	Rule 47 / 48 Correction of Inventorship Papers Filed	
09-12-2006	Date Forwarded to Examiner	
08-28-2006	Response after Non-Final Action	92
08-28-2006	Request for Extension of Time - Granted	⬆
04-19-2006	Mail-Petition Decision - Granted	⬆
04-18-2006	Correspondence Address Change	⬆
04-19-2006	Change in Power of Attorney (May Include Associate POA)	⬆
04-19-2006	Change in Power of Attorney (May Include Associate POA)	⬆
08-18-2005	Petition Entered	⬆
02-28-2006	Mail Non-Final Rejection	⬆
02-24-2006	Non-Final Rejection	
01-03-2006	Date Forwarded to Examiner	
12-09-2005	Response after Non-Final Action	85
12-09-2005	Request for Extension of Time - Granted	⬆
01-03-2006	Correspondence Address Change	⬆
06-15-2005	Mail Non-Final Rejection	⬆
06-13-2005	Non-Final Rejection	
05-23-2005	Date Forwarded to Examiner	
05-16-2005	Response to Election / Restriction Filed	
04-13-2005	Mail Restriction Requirement	83
04-12-2005	Requirement for Restriction / Election	⬆
12-14-2004	Reference capture on IDS	⬆

12-14-2004	Information Disclosure Statement (IDS) Filed	⬆	
12-14-2004	Information Disclosure Statement (IDS) Filed	⬆	
09-24-2004	Case Docketed to Examiner in GAU	⬆	
09-24-2004	IFW TSS Processing by Tech Center Complete	⬆	
11-20-2003	Reference capture on IDS	⬆	
11-20-2003	Information Disclosure Statement (IDS) Filed	⬆	
11-20-2003	Information Disclosure Statement (IDS) Filed	⬆	
11-20-2003	Preliminary Amendment	⬆	
05-25-2004	Application Return from OIPE	⬆	
05-25-2004	Application Return TO OIPE	⬆	
05-24-2004	Application Dispatched from OIPE	⬆	
05-25-2004	Application Is Now Complete	⬆	
05-13-2004	Payment of additional filing fee/Preexam		34
04-28-2004	Transfer Inquiry to GAU	⬆	
01-09-2004	Notice Mailed--Application Incomplete--Filing Date Assigned	⬆	
01-05-2004	Cleared by OIPE CSR		
12-25-2003	IFW Scan & PACR Auto Security Review		
11-20-2003	Initial Exam Team nn		

Close Window

EXHIBIT C:

***Wyeth et al. v. Dudas*, Civil Action No. 07-1492 (JR), United States District Court for the
District of Columbia, 2008 U.S. Dist. LEXIS 76063 (D.D.C., September 30, 2008)**

1 of 1 DOCUMENT

**WYETH, et al., Plaintiffs, v. JON W. DUDAS, Under Secretary of Commerce for
Intellectual Property and Director of U.S. Patent and Trademark Office, Defendant.**

Civil Action No. 07-1492 (JR)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

2008 U.S. Dist. LEXIS 76063

September 30, 2008, Filed

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For JON W. DUDAS, Honorable, Under Secretary of Commerce, Defendant: Fred Elmore Haynes, LEAD ATTORNEY, U.S. ATTORNEY'S OFFICE, Washington, DC.

JUDGES: JAMES ROBERTSON, United States District Judge.

OPINION BY: JAMES ROBERTSON

OPINION

MEMORANDUM OPINION

Plaintiffs here take issue with the interpretation that the United States Patent and Trademark Office (PTO) has imposed upon 35 U.S.C. § 154, the statute that prescribes patent terms. *Section 154(a)(2)* establishes a term of 20 years from the day on which a successful patent application is first filed. Because the clock begins to run on this filing date, and not on the day the patent is actually granted, some of the effective term of a patent is consumed by the time it takes to prosecute the application. To mitigate the damage that bureaucracy can do to inventors, the statute grants extensions of patent terms for certain specified kinds of PTO delay, 35 U.S.C. § 154(b)(1)(A), and, regardless of the reason, whenever the patent prosecution [*2] takes more than three years. 35 U.S.C. § 154(b)(1)(B). Recognizing that the protection provided by these separate guarantees might overlap,

Congress has forbidden double-counting: "To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A). Plaintiffs claim that the PTO has misconstrued or misapplied this provision, and that the PTO is denying them a portion of the term Congress has provided for the protection of their intellectual property rights.

Statutory Scheme

Until 1994, patent terms were 17 years from the date of issuance. *See* 35 U.S.C. § 154 (1992) ("Every patent shall contain . . . a grant . . . for the term of seventeen years . . . of the right to exclude others from making, using, or selling the invention throughout the United States. . . ."). In 1994, in order to comply with treaty obligations under the General Agreement on Tariffs and Trade (GATT), the statute was amended to provide a 20-year term from the date on which the application is first filed. *See* Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994). [*3] In 1999, concerned that extended prosecution delays could deny inventors substantial portions of their effective patent terms under the new regime, Congress enacted the American Inventors Protection Act, a portion of which -- referred to as the Patent Term Guarantee Act of 1999 -- provided for the adjustments that are at issue in this case. Pub. L. No. 106-113, §§ 4401-4402, 113 Stat. 1501, 1501A-557 (1999).

As currently codified, 35 U.S.C. § 154(b) provides three guarantees of patent term, two of which are at issue here. The first is found in *subsection (b)(1)(A)*, the "[g]uarantee of prompt Patent and Trademark Office response." It provides a one-day extension of patent term for every day that issuance of a patent is delayed by a failure of the PTO to comply with various enumerated

statutory deadlines: fourteen months for a first office action; four months to respond to a reply; four months to issue a patent after the fee is paid; and the like. *See* 35 U.S.C. § 154(b)(1)(A)(i)-(iv). Periods of delay that fit under this provision are called "A delays" or "A periods." The second provision is the "[g]uarantee of no more than 3-year application pendency." Under this provision, a one-day [*4] term extension is granted for every day greater than three years after the filing date that it takes for the patent to issue, regardless of whether the delay is the fault of the PTO.¹ *See* 35 U.S.C. § 154(b)(1)(B). The period that begins after the three-year window has closed is referred to as the "B delay" or the "B period". ("C delays," delays resulting from interferences, secrecy orders, and appeals, are similarly treated but were not involved in the patent applications underlying this suit.)

1 Certain reasons for exceeding the three-year pendency period are excluded, *see* 35 U.S.C. § 154(b)(1)(B)(i)-(iii), as are periods attributable to the applicant's own delay. *See* 35 U.S.C. § 154(b)(2)(C).

The extensions granted for A, B, and C delays are subject to the following limitation:

(A) In general.--To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. § 154(b)(2)(A). This provision is manifestly intended to prevent double-counting of periods of delay, but understanding that intent does not answer [*5] the question of what is double-counting and what is not. Proper interpretation of this proscription against windfall extensions requires an assessment of what it means for "periods of delay" to "overlap."

The PTO, pursuant to its power under 35 U.S.C. § 154(b)(3)(A) to "prescribe regulations establishing procedures for the application for and determination of patent term adjustments," has issued final rules and an "explanation" of the rules, setting forth its authoritative construction of the double-counting provision. The rules that the PTO has promulgated essentially parrot the statutory text, *see* 37 C.F.R. § 1.703(f), and so the real interpretive act is found in something the PTO calls its Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. § 154(b)(2)(A), which was published on June 21, 2004, at 69 Fed. Reg. 34238. Here, the PTO "explained" that:

the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under [*6] 35 U.S.C. § 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. § 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

69 Fed. Reg. 34238 (2004) (emphasis added). In short, the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for "A delay" or for "B delay," whichever is larger, but never A + B.

In the plaintiffs' submission, this interpretation does not square with the language of the statute. They argue that the "A period" and "B period" overlap only if they occur on the same calendar day or days. Consider this example, proffered by plaintiff: A patent application is filed on 1/1/02. The patent issues on 1/1/08, six years later. In that six-year period are two "A periods," each one year long: (1) the 14-month deadline for first office action is 3/1/03, but the first office action does not occur until 3/1/04, one year late; (2) the 4-month deadline for patent issuance after payment of the issuance fee is 1/1/07, but the patent does not [*7] issue until 1/1/08, another year of delay attributable to the PTO. According to plaintiff, the "B period" begins running on 1/1/05, three years after the patent application was filed, and ends three years later, with the issuance of the patent on 1/1/08. In this example, then, the first "A period" does not overlap the "B period," because it occurs in 2003-04, not in 2005-07. The second "A period," which covers 365 of the same days covered by the "B period," does overlap. Thus, in plaintiff's submission, this patent holder is entitled to four years of adjustment (one year of "A period" delay + three years of "B period" delay). But in the PTO's view, since "the entire period during which the application was pending before the office" is considered to be "B period" for purposes of identifying "overlap," the patent holder gets only three years of adjustment.

Chevron Deference

We must first decide whether the PTO's interpretation is entitled to deference under *Chevron v. NRDC*, 467 U.S. 837, 104 S. Ct. 2778, 81 L. Ed. 2d 694 (1984). No,

the plaintiffs argue, because, under the Supreme Court's holdings in *Gonzales v. Oregon*, 546 U.S. 243, 126 S. Ct. 904, 163 L. Ed. 2d 748 (2006), and *United States v. Mead Corp.*, 533 U.S. 218, 121 S. Ct. 2164, 150 L. Ed. 2d 292 (2001), Congress has not "delegated [*8] authority to the agency generally to make rules carrying the force of law," and in any case the interpretation at issue here was not promulgated pursuant to any such authority. See *Gonzales*, 546 U.S. at 255-56, citing *Mead*, 533 U.S. at 226-27. Since at least 1996, the Federal Circuit has held that the PTO is not afforded *Chevron* deference because it does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency. See *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996).

Here, as in *Merck*, the authority of the PTO is limited to prescribing "regulations establishing procedures for the application for and determination of patent term adjustments under this subsection." 35 U.S.C. § 154(b)(3)(A) (emphasis added). Indeed, a comparison of this rulemaking authority with the authority conferred for a different purpose in the immediately preceding section of the statute makes it clear that the PTO's authority to interpret the overlap provision is quite limited. In 35 U.S.C. § 154(b)(2)(C)(iii) the PTO is given the power to "prescribe regulations establishing the circumstances that constitute a failure of an applicant [*9] to engage in reasonable efforts to conclude processing or examination of an application" (emphasis added) -- that is, the power to elaborate on the meaning of a particular statutory term. No such power is granted under § 154(b)(3)(A). *Chevron* deference does not apply to the interpretation at issue here.

Statutory Construction

Chevron would not save the PTO's interpretation, however, because it cannot be reconciled with the plain text of the statute. If the statutory text is not ambiguous enough to permit the construction that the agency urges, that construction fails at *Chevron's* "step one," without regard to whether it is a reasonable attempt to reach a result that Congress might have intended. See, e.g., *MCI v. AT&T*, 512 U.S. 218, 229, 114 S. Ct. 2223, 129 L. Ed. 2d 182 (1994) ("[A]n agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear.").

The operative question under 35 U.S.C. § 154(b)(2)(A) is whether "periods of delay attributable to grounds specified in paragraph (1) overlap." The only way that periods of time can "overlap" is if they occur on the same day. If an "A delay" occurs on one calendar day and a "B delay" occurs on another, they do not [*10] overlap, and § 154(b)(2)(A) does not limit the extension to one day. Recognizing this, the PTO defends its inter-

pretation as essentially running the "period of delay" under subsection (B) from the filing date of the patent application, such that a period of "B delay" *always overlaps* with any periods of "A delay" for the purposes of applying § 154(b)(2)(A).

The problem with the PTO's construction is that it considers the application *delayed* under § 154(b)(1)(B) during the period *before it has been delayed*. That construction cannot be squared with the language of § 154(b)(1)(B), which applies "if the issue of an original patent is *delayed* due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years." (Emphasis added.) "B delay" begins when the PTO has failed to issue a patent within three years, not before.

The PTO's interpretation appears to be driven by Congress's admonition that any term extension "not exceed the actual number of days the issuance of the patent was delayed," and by the PTO's view that "A delays" during the first three years of an applications' pendency inevitably lead to "B delays" in later years. Thus, as the PTO sees it, if [*11] plaintiffs' construction is adopted, one cause of delay will be counted twice: once because the PTO has failed to meet an administrative deadline, and again because that failure has pushed back the entire processing of the application into the "B period." Indeed, in the example set forth above, plaintiffs' calendar-day construction does result in a total effective patent term of 18 years under the (B) guarantee, so that -- again from the PTO's viewpoint -- the applicant is not "compensated" for the PTO's administrative delay, he is benefited by it.

But if subsection (B) had been intended to guarantee a 17-year patent term and *no more*, it could easily have been written that way. It is true that the legislative context -- as distinct from the legislative history -- suggests that Congress may have intended to use subsection (B) to guarantee the 17-year term provided before GATT. But it chose to write a "[g]uarantee of no more than 3-year application pendency," 35 U.S.C. § 154(b)(1)(B), not merely a guarantee of 17 effective years of patent term, and do so using language separating that guarantee from a different promise of prompt administration in subsection (A). The PTO's efforts to [*12] prevent windfall extensions may be reasonable -- they may even be consistent with Congress's intent -- but its interpretation must square with Congress's words. If the outcome commanded by that text is an unintended result, the problem is for Congress to remedy, not the agency.

JAMES ROBERTSON

United States District Judge